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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/791,753	03/04/2004	Tsutomu Fujimura	249976US0	5264	
<sup>22850</sup> 01/16/2009 01/16/2009 01/16/2009 0ELON, SPIVAK, MCCLEILLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET			EXAM	EXAMINER	
			LEITH, PATRICIA A		
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER	
			1655		
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

## Application No. Applicant(s) 10/791,753 FUJIMURA, TSUTOMU Office Action Summary Examiner Art Unit Patricia Leith 1655 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 October 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-6 and 8-17 is/are pending in the application. 4a) Of the above claim(s) 1-3.5.8.9.11 and 13 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 4, 6, 10, 12, 14 and 15-17 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other:

#### DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2008 has been entered.

Claims 1-6 and 8-17 are pending in the application.

Claims 1-3, 5, 8, 11 and 13 remain withdrawn from examination on the merits. It is noted that Applicants have struck all of the species from the claims save for Digeneasimplex (*Digenea simplex*) which is, by default, the species examined on its merits. The species of 'extract' is still being examined, and hence, claims directed solely toward a plant part or plant is withdrawn as in the previous Office action.

It is noted that claim 9 is withdrawn; however, Applicant has included the status identifier of '(Currently Amended).' Applicant is asked to correct this deficiency in the next correspondence.

Art Unit: 1655

Claims 4, 6, 10, 12, 14 and 15-17 were examined on their merits.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6, 10, 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopes (US 5,942,478) in light of SigmaAldrich (1996)\*.

Lopes teaches microbicidal and sanitizing soaps for topical administration to the skin (see entire reference and Abstract). More specifically, Lopes includes, as a 'skin-

Art Unit: 1655

lubricating and skin-protecting agent' including 'agar-agar', see, for example, col. 2, lines 1-38 and more specifically, col. 2, line 27; see also claim 18 which specifically claims an a bactericidal and antimicrobial soap for topical use which contains agar-agar as the skin-lubricating/skin-protecting agent in an amount of 0.1 to 25% by weight of the composition). Claim 12 specifically claims the soap in a gel or a liquid form which meets the limitations of claims 10 and 17. It is noted that the recitation of agar-agar in claim 18 of Lopes for example, is an explicit description of an embodiment containing agar-agar. Markush-type language in claims is merely a means for Applicants to claim numerous embodiments without having to expressly write alternative embodiments in many, many independent claims. Hence, every alternative species present in the Markush group as claimed in Lopes is considered a specific, patentable embodiment.

SigmaAldrich teaches that *Digenea simplex* mucilage (an extract of *Digenea simplex*) is a polysaccharide complex also known as agar, agar-agar, gum agar and Gelose for example (see pp. 1-2). Therefore, the 'agar-agar' (a.k.a '*Digenea simplex* mucilage') of Lopes meets the description of a *Digenea simplex* extract.

Lopes does not explicitly teach wherein the amount of extract used (as reduced to dry weight) is 0.00001 to 5% based on the total amount of the agent, or wherein the agent is applied to the skin in an amount of from 0.01 to 10 mg/cm<sup>2</sup>.

Art Unit: 1655

The ordinary artisan would have had a reasonable expectation that the method of Lopes would have carried out the function of 'increasing an expression level of Rho kinase or myosin light-chain kinase' because the only step which achieves this requirement, as recited by the claims, is by contacting the skin with a skin improving agent. Clearly, the composition of Lopes which includes agar-agar as a skin conditioning/lubricating agent is a 'skin improving agent' and would therefore be expected to fulfill the functional language of 'increasing an expression level of Rho kinase or myosin light-chain kinase' absent evidence to the contrary:

"As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

It is clear that the amount of agar in the claims of Lopes overlaps with the claimed amount of extract; i.e., Lopes teaches 0.1 to 25%, while the claims teach 0.00001 to 5%, thus rendering obvious the claimed amount. Absent any showing of an unexpected results, ranges overlapping with those of Lopes are deemed to be values

achieved upon routine experimentation, such experimentation being within the skill level of the ordinary artisan at the time the invention was made.

Although the prior art does not specifically teach the measurements of the surface area to be treated, the ordinary artisan would have been motivated to vary the amount of product administered to the skin dependant on the amount of surface area in need of treatment in order to maximize efficacy of the cosmetic composition.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable varition...103 likely bars its patentability...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### Conclusion

Art Unit: 1655

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith Primary Examiner Art Unit 1655

/Patricia Leith/ Primary Examiner, Art Unit 1655

Page 8

Art Unit: 1655